IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

In re.: Heparin	MDL 1953
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Suzanne Monroe,	Case No. 3:09HC60137
Plaintiff	
v.	ORDER
Baxter Healthcare Corp., et al.,	
Defendants	

This is a contract and tort suit brought in the context of multi-district litigation about adulterated heparin. Plaintiff Suzanne Monroe, Administratrix of decedent Vincent Franciamone's estate, alleges that defendant Gambro Renal Products [Gambro] manufactured a defective cartridge blood tubing set, the use of which resulted in decedent's death.

Plaintiff asserts eight causes of action against Gambro: 1) defective manufacturing; 2) design defect; 3) defect due to inadequate warning; 4) breach of implied warranty; 5) breach of express warranty; 6) negligence; 7) fraudulent misrepresentation; and 8) wrongful death.

Jurisdiction is proper under 28 U.S.C. § 1332.

Pending is Gambro's motion to dismiss. [Doc. 8]. For the reasons discussed below, Gambro's motion shall be granted.

Background

Defendant Gambro manufactures dialysis machines, including cartridge blood tubing sets.

From approximately August, 2007, until his death on October 16, 2007, decedent underwent dialysis treatments using a Gambro dialysis machine to receive heparin.

On September 10, 2007, Gambro initiated a Class II Recall of the Gambro cartridge blood tubing sets because kinked tubing on the hemodialysis devices could cause hemolysis.[1]

On October 16, 2007, decedent was found deceased at home. His death certificate listed his cause of death as "acute exsanguination due to a ruptured arteriovenous dialysis graft in his right arm." [Doc. 1, at 16].

Standard of Review

A claim survives a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) if it "contain[s] sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, U.S. , 129 S. Ct. 1937, 1949 (2009). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* A complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all of the complaint's allegations are true." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007) (internal citations omitted).

I must also "construe the complaint in the light most favorable to the plaintiff." *Inge v. Rock*

[1] "Hemolysis" is defined as "(t)he alteration, dissolution or destruction of red blood cells." [Doc. 8, at 9 n.3].

Fin. Corp., 281 F.3d 613, 619 (6th Cir. 2002). Plaintiff, however, must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, *supra*, 550 U.S. at 555; *see also Iqbal*, 129 S.Ct. at 1949 ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice."); *Hensley Mfg. v. ProPride, Inc.*, 579 F. 3d 603, 609 n.4 (6th Cir. 2009) (stating that *Twombly* applies to all civil actions).

Discussion

Gambro argues that plaintiff's complaint should be dismissed for failure to state a claim on which relief may be granted, because the complaint does not allege facts establishing Gambro's product as the proximate cause of decedent's death. Gambro claims that plaintiff never specifically alleges an incident of "kinking" in any cartridge blood tubing in a machine used in conjunction with administration of heparin to the decedent or that such an incident caused the death of decedent.

Plaintiff responds that her complaint satisfies the pleading requirements set out by Fed. R. Civ. P. 8, and that the level of specificity defendant seeks "is not required under the Federal Rules [of Civil Procedure]." [Doc. 11, at 12]. In alleging causation, plaintiff points primarily to inclusion of the words "[a]s a direct and proximate result" in her claims against Gambro. Plaintiff asserts that her identification of Gambro's recall, coupled with the circumstances surrounding decedent's death, enables her to survive Gambro's motion to dismiss.

Proximate causation is a required element of each of plaintiff's claims. *See Bellevue S. Assocs. v. HRH Constr. Corp.*, 579 N.E.2d 195, 203 (N.Y. 1991) (proximate causation is a required element of breach of warranty claims); *Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204, 209 (N.Y. 1983) (proximate causation is a required element of a design defect claim); *Kush by Marszalek v.*

City of Buffalo, 449 N.E.2d 725, 729 (N.Y. 1983) (proximate causation is a required element of a negligence claim); *Roth v. Zelig*, 883, N.Y.S.2d 550, 551 (App. Div. 2009) (proximate causation is a required element of a wrongful death claim); *Safchik v. Prudential Sec., Inc.*, 650 N.Y.S.2d 569, 570 (App. Div. 1996) (proximate causation is a required element of a fraudulent misrepresentation claim); *Buck v. Reed*, 647 N.Y.S.2d 581, 582 (App. Div. 1996) (proximate causation is a required element of a manufacturing defect claim); *Banks v. Makita, U.S.A., Inc.*, 641 N.Y.S.2d 875, 877 (App. Div. 1996) (proximate causation is a required element of an inadequate warning claim).

Plaintiff must thus allege that Gambro's defective product proximately caused decedent's death to survive a motion to dismiss for failure to state a claim.

In her complaint, plaintiff claims, in relevant part:

> 55. On or about September 10, 2007, Gambro initiated a Class 2 Recall of the Gambro cartridge blood tubing set due to the fact that "kinked tubing on hemodialysis may cause hemolysis."
>
> . . .
>
> 60d. If Defendant Gambro had complied with federal requirements regarding CGMP, Defendant's cartridge blood tubing set would have been manufactured properly such that it would not have caused adverse events, including hemolysis and death.
>
> . . .
>
> 66. As a direct and proximate result of the defective Gambro cartridge blood tubing sets used during his dialysis treatments, and the attendant medical symptoms he then suffered, Decedent Vincent Franciamone suffered physical injury, including conscious pain and suffering and ultimately death on October 16, 2007.
>
> . . .
>
> 169. Defendant Franciamone received dialysis treatments on numerous occasions during which time he was treated with and exposed to a defective and unreasonably dangerous medical device manufactured, designed, distributed, sold and supplied by Defendant Gambro.

[Doc. 1, at 14, 16, 17, 34].

Here, the relevant language in plaintiff's complaint does not adequately allege proximate causation. Plaintiff refers vaguely to failures to comply with federal requirements, hemolysis, and Gambro's Class II recall. She also summarily states that decedent's injuries and death resulted "[a]s a direct and proximate result" of Gambro's actions.

This, however, is no more than "formulaic recitation of the elements of a cause action, " and is insufficient to survive a motion to dismiss. *Twombly*, *supra*, 550 U.S. at 555. Plaintiff never specifically alleges that decedent's dialysis machine had kinked tubing, nor ties the possible result of kinked tubing—hemolysis—to decedent's actual cause of death: acute exsanguination due to ruptured arteriovenous dialysis graft in his right arm.

Plaintiff's complaint therefore fails to allege adequately proximate causation, and must be dismissed.

Conclusion

For the foregoing reasons, it is hereby:

ORDERED THAT Gambro's motion to dismiss [Doc. 8] be, and the same hereby is, granted as to all counts.

So ordered.

S/James G. Carr
James G. Carr
Chief Judge